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10/693,398	10/24/2003	Lee A. Core	106586-172 US2	2513
23483	7590	03/18/2009	EXAMINER	
WILMERHALE/BOSTON			TRUONG, KEVIN THAO	
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BOSTON, MA 02109			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/693,398	Applicant(s) CORE, LEE A.	
	Examiner Kevin T. Truong	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 13-18, 20, 21 and 26-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 13-18, 20-21, and 26-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Note: This is in response to the amendment filed 09/29/2008.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 13-15, 26-31, 38, 45-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Berg et al. (US 6858024).

Note in figures 11-14, a conduit (54) having inner layer (74) and outer layer (18), wherein the durometer of the inner layer (74) is greater than the durometer of the outer layer (18) and ranges on a scale of inner and outer layers (74,18) (see col. 10, lines 16-34); wherein the circumference of the inner layer is discontinuous so as to form a discontinuity and is non-overlapping (at (66) as shown in figures 11A-11C); and the circumference of the outer layer is continuous and extends between the discontinuity (at 66) of the inner layer (74); wherein the different elastic sections (74,18) comprising resilient material and capable of allowing the conduit (54) to expand temporarily in the radial direction.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 16-18, 20-21, 32-44, and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (US 5318588) in view of Berg et al. (6858024). Horzewski et al. disclose the invention as claimed including a conduit for insertion into a body through which another device passes with two layers bonded together and the inner layer having a higher durometer than the outer layer (col. 7, line 40-41, 51-54; ref. 5-7, 11 and 14, Fig. 1A-1D), the inner layer being discontinuous by means of a slit (see ref. 13) and the outer layer being continuous (see Fig. 1B), the conduit being an introducer sheath or a catheter (obvious variations of one another), a medical device with an outer diameter greater than the inner layer diameter for insertion through the conduit (see bulge in Fig. 2A-2F) and wherein the conduit expands as the medical device passes through it, and a method of using the device (see Fig. 2A-2F). Horzewski et al. do not disclose a conduit having an inner layer forms a discontinuity and is non-overlapping and also a portion of the outer layer extends between the discontinuities. Berg teaches in figures 11-14 that it is known in the surgical art to have a conduit having an inner layer forms a discontinuity and is non-overlapping and also a portion of the outer layer extends between the discontinuity (as state in the 102 rejection above) .

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Therefore, it would have been obvious to one having ordinary skill in the art to have modified Horzewski et al. with an inner layer forms a discontinuity and is non-overlapping and also a portion of the outer layer extends between the discontinuity, as taught by Berg et al, in order to allow the conduit to expand radially as a medical device is passed through it.

As to claims 40-41 and 43-44, Horzewski et al. disclose the invention substantially as claimed except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent, blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. Stents, blood clot filter, and occluder are well-known devices to be inserted through a conduit and into a lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a body lumen. Howzeski et al. also disclose a conduit that has third and fourth types of section in a circumferential direction. Although the layers are oriented with one layer outside the other layer, they are still comprised of first through fourth types of sections in a circumferential direction (see Fig. 1 above).

As to claims 53-56, Horzewski et al. disclose the invention substantially as claimed

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except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent, blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. The other geometric formations are obvious variation of having a slit and/or an overlapping section that would obtain the same results of expanding the inner layer of the conduit. Stents, blood clot filter, and occluder are well-known devices to be inserted through a conduit and into a lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. with a different geometric formation of the inner layer of the conduit and with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a body lumen.

Response to Arguments

5. Applicant's arguments filed 09/29/2008 have been fully considered but they are not persuasive. Applicant's arguments with respect to claims 1-5, 13-18, 20-21, and 26-56 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kondo (US 5746696) discloses a flexible sheathing tube having multiple layers.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin T. Truong whose telephone number is 571-272-4705. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Kevin T. Truong
Primary Examiner
Art Unit 3734